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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,027	03/02/2004	John A. Giordano	48508-00014	9737

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,027	GIORDANO ET AL.	
	Examiner	Art Unit	
	Frank I Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *187-201 and 217-231* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *187-201 and 217-231* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/27/2004, 3/2/2004
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 3/22/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed and fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office in that the documents filed with the IDS and listed under foreign patent documents are not foreign patent documents but are abstracts of said foreign patent documents which should be listed under other prior art. Except for said documents, the IDS has been considered.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See paragraphs 0041-0043, 0046,0047 of the Specification.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 187-201 are rejected under 35 U.S.C. 102(e) as being anticipated by Nidamarty et al. (US 2003/0206969).

Nidamarty et al. expressly discloses a composition containing Vitamin A (beta-carotene), Vitamin D (cholecalciferol), Vitamin C (ascorbic acid), Vitamin E (dl-alph tocopheryl acetate), folic acid, Vitamin B1 (thiamine mononitrate), Vitamin B2 (riboflavin), Vitamin B6 (pyridoxine hydrochloride), Vitamin B12 (cyanocobalamin), niacin (niacinamide), calcium (calcium carbonate), iron (ferrous fumarate, ferrous bis-glycinate), magnesium (magnesium oxide), zinc (zinc oxide), and copper (cupric oxide). as a dietary supplement (Nidamarty et al., paragraphs 0050-0051, Claim 38).

Claims 187-201,217-231 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nidamarty et al. (US 2003/0206969).

Nidamarty et al. discloses a composition containing Vitamin A (beta- carotene) (about 0 – 6500 IU, about 1-7500 IU, about 4000-4500 IU, 3000 IU), Vitamind (cholecalciferol) (about 1-600 IU, 400 IU), Vitamin C (ascorbic acid) (about 10-1000 mg, about 130-160 mg, 120 mg), Vitamin E (dl-alpha-tocopheryl acetate) (about 1-100 IU, about 36.5 IU, about 0.8-80 IU, 24 IU), Vitamin B1 (thiamine mononitrate) (about 0.5-50 mg, about 2.0 –2.5 mg, 1.8 mg), Vitamin B2 (riboflavin) (about 0.5-50 mg, , about 4.5-5.5 mg, 4 mg), Vitamin B6 (pyridoxine hydrochloride) (about 0.1-200 mg, about 40-45 mg, 25 mg), Vitamin B12 (cyanocobalamine) (about 2 –250 mcg, 12 mcg), niacin

(niacinamide) (about 1-100 mg, 20 mg), calcium (calcium carbonate) (about 20-1000 mg, about 80-110 mg, 100 mg), iron (iron-amino acid chelate or iron-amino acid chelate/ferrous fumarate) (total iron - about 5-200 mg, 29 mg; ferrous fumarate provides 1%-25%-75%-99% of said about 5 –200 mg of total iron, provides 1%-25%-75%-99% of said 29 mg of total iron), magnesium oxide (about 0.1-400 mg, about 0-400 mg, 25 mg), zinc oxide (about 5-100 mg, about 30-35 mg, 25 mg) and cupric oxide (about 0.1-10 mg, about 2.3 –3.0 mg, about 0-10 mg, 2 mg) as a dietary supplement (Nidamarty et al., paragraphs 0028-0052, Claim 38).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the claimed amounts of vitamins and minerals within the scope of about 2430 IU to about 2970 IU Vitamin A, about 63 mg to about 77 mg Vitamin C, about 27 IU to about 33 IU Vitamin E, about 1.44 mg to about 1.76 mg Vitamin B1, about 1 .62 mg to about 1 .98 mg Vitamin B2, about 2.25 mg to about 2.75 mg Vitamin B6, about 58.5 mg to about 71.5 mg iron wherein said composition is free of any other added minerals and any other added vitamins other than Vitamin A, Vitamin D, Vitamin C, Vitamin E, folic acid, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, niacin, calcium, iron, magnesium, zinc, and copper. However, the prior art amply suggests the same as amounts near and/or encompassing the claimed amounts are disclosed by the prior art and embodiments are taught which only contain Vitamin A (beta-carotene), Vitamin D (cholecalciferol), Vitamin C (ascorbic acid), Vitamin E (dl-alph tocopheryl acetate), folic acid, Vitamin B1 (thiamine mononitrate), Vitamin B2 (riboflavin), Vitamin B6 (pyridoxine hydrochloride), Vitamin B12 (cyanocobalamin),

niacin (niacinamide), calcium (calcium carbonate), iron (ferrous fumarate, ferrous bis-glycinate), magnesium (magnesium oxide), zinc (zinc oxide), and copper (cupric oxide).

As such, it would have been well within the skill of one of ordinary skill in the art to modify the prior art depending on the amount of each vitamin or mineral desired in the composition with the expectation that said amount would be suitable for use in a dietary supplement (See In re Peterson, 65 USPQ2d 1379, 1382, 1383 (CAFC 2003) (a *prima facie* case of obviousness exists where the ranges overlap, are close enough such that one of ordinary skill in the art would expect them to have the same properties or where a somewhat broader range encompasses the claimed narrower range).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 187, 217 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45,46,287,288 of

copending Application No. 10/315,159. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both set forth compositions containing the same vitamins and minerals with claims 45,46,287,288 of Application No. 10/315,159 anticipating claims 187, 217 by claiming amounts which are encompassed by the scope of the claims 187,217.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 187-201, 217-231 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45,46,287,288 of copending Application No. 10/315,159 in view of Manning et al. (US Pat. 6,569,445) or Nidamarty et al. (US 2003/0206969).

Claims 45,46,287,288 disclose a composition comprising Vitamin A, Vitamin D, Vitamin C, Vitamin E, folic acid, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, niacin, calcium, iron, magnesium, zinc, and copper, wherein said composition is administrable to a patient, and wherein said composition is free of any other added minerals and any other added vitamins.

Manning et al. or Nidamarty et al. discloses that the use of vitamins and minerals such as beta-carotene, cholecalciferol, ascorbic acid, dl-alpha-tocopheryl acetate, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamine, niacinamide, calcium carbonate, ferrous fumarate, magnesium oxide, zinc oxide, cupric oxide as a dietary supplement (Manning et al., Column 7, lines 60-68, Column 8, Column 9, lines 1-10; Nidamarty et al., paragraphs 0035-0052).

The difference between the claims of the'159 Application and the claimed invention is that said claims do not expressly disclose the specific forms of Vitamin A, Vitamin D, Vitamin C, Vitamin E, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, niacin, calcium, iron, magnesium, zinc, and copper set forth in the dependent claims 188-201, 218-231. However, the prior art amply suggests the same as said specific forms are disclosed in the cited prior art to be useful as a dietary supplement. As such, one of ordinary skill in the art would have been motivated to modify the claims of the '159 Application by using the specified forms of the vitamins and minerals disclosed in Manning et al. or Nidamarty et al. with the expectation that the resulting composition would be suitable for use as a dietary supplement.

Therefore, the claimed invention, as a whole, would have been obvious modification of the claims of the '159 Application to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of said claims and the cited prior art.

This is a provisional obviousness-type double patenting rejection.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC
August 7, 2004

JOHN PAK
PRIMARY EXAMINER
GROUP 1600